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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/728,078	12/03/2003	Dasa Lipovsek	COTH-P04-507	7953

7590

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Patent Group  
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EXAMINER
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AUDET, MAURY A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/728,078

Applicant(s)

LIPOVSEK ET AL

Examiner

Maury Audet

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

#### **SET I: Non-Antibody Protein, Nucleic Acid, or Process of Making or Using**

1. Claims 1-25, and 32, drawn to a non-antibody protein, classified in class 530, subclass 300+.
2. Claims 26-29, drawn to a non-antibody protein joined to a heterologous protein (i.e. antibody protein), classified in class 530, subclass 300+, class 530, subclass 387.1.
3. Claims 30-31, drawn to a non-antibody protein covalently bound to a nucleic acid, classified in class 530, subclass 300+, class 536, subclass 23.1.
4. Claim 33, drawn to a nucleic acid, classified in class 536, subclass 23.1.
5. Claim 34, drawn to a process of making a derivative non-antibody protein utilizing a scaffold protein, classified in class 530, subclass 333 and/or 344.
6. Claim 35, drawn to a process of making a derivative non-antibody protein utilizing a candidate protein, classified in class 530, subclass 333 and/or 344.
7. Claims 36, drawn to a process of making a compound that binds to a non-antibody (candidate protein), classified in class 530, subclass 333 and/or 344.

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8. Claims 37, drawn to a process of using (detecting) a compound in a sample, classified in class 530, subclass 333 and/or 344.

The inventions of SET I are distinct, each from the other because of the following reasons:

The compound of Invention 2 is related to the non-antibody protein of Invention 1 by virtue of also containing the non-antibody protein. However, the compound of Invention 2 and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

The compound of Invention 3 is related to non-antibody protein of Invention 1 by virtue of containing the non-antibody protein. However, the compound of Invention IV and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

The nucleic acid of Invention 4 is related to the non-antibody protein of Invention 1 by virtue of encoding same. However, the compound of Invention 4 and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

Invention 1 and Inventions 5-6 are related as product and process of making. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process as claimed is not an obvious process of making the product and the process as claimed can be used to make other and different products; (2) the product as claimed can be made by another and materially different process. (MPEP section 806.05(f)). In the instant case, the product, as claimed, could be made by the materially different process of recombinant production or chemical synthesis.

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Invention 8 and Invention 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP section 806.05(h)). In the instant case the product as claimed can be used in the materially different process of affinity purification of antibodies.

**SET II: Non-Antibody Protein, Loop Structure (SEQ ID NOS: 38-140)**

- 9.-111. Claims 38-41, and 43, drawn to a non-antibody protein/loop structure that binds tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), wherein said protein comprises any one of SEQ ID NOS: 38-140, classified in class 530, subclass 300.

Inventions 9-111 of SET II are drawn to non-antibody proteins (and loop structures therein) that differ in structure and in function. Therefore, each protein is patentably distinct one from the other. If any one of Inventions 9-111 is elected, the examination of the claims will be carried out only in-so-far as the claims are drawn to the elected invention.

**SET III: Nucleic Acid**

112. Claim 42, drawn to a nucleic acid encoding a non-antibody protein that binds tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ), classified in class 536, subclass 23.1.

The inventions of SET II-III are distinct, each from the other because of the following reasons:

The nucleic acids of Invention 105 are related to the non-antibody proteins/loop structures of Inventions 9-111 by virtue of encoding same. However, the compound of Invention

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4 and the non-antibody protein of Invention I differ in structure (chemically, physically, or pharmacologically) and in function.

***Election of a Single Method of Using Single Peptide***

In addition to electing single group, Applicant is required to elect a peptide as drawn to any of the groups, to which the elected invention will be examined on the merits (i.e. SEQ ID NO: 34), because no meaningful search can be conducted without a undue burden, due to the myriad of peptides to which the inventions may be drawn. Thus, a separate and distinct search, as well as examination of each Formula and method of use is required. **This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each method is assumed to be patentably distinct invention, in the absence of evidence to the contrary.**

**Summary: Requirement for Restriction**

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

#### ***In re Ochiai/Brouwer Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

#### **Request for Preliminary Set of Amended Claims**

Based on the claims as originally filed, there are many dependencies among the different inventions identified above. As part of the election, Applicant is requested to submit a

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preliminary set of amended claims, directed to the elected invention, which do not contain any dependencies to any other non-elected inventions (claims), and which are fully descriptive of and include all limitations to that set of claims representing the elected invention.

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 02/05/2005



CHRISTOPHER R. TATE  
PRIMARY EXAMINER